

200315586-1

10/827,484

REMARKS

This is a full and timely response to the non-final Official Action mailed **February 11, 2008** (the "Office Action" or "Action"). Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

Under the imposition of a previous Restriction Requirement, claims 6, 17-54 and 57-59 were withdrawn. To expedite the prosecution of this application, withdrawn claims 21-54 and 57-59 are cancelled by the present paper without prejudice or disclaimer. Applicant reserves the right to file continuation or divisional applications as permitted by 37 C.F.R. to the withdrawn claims or to any other subject matter described in the present application.

The other withdrawn claims depend from elected claim 1 and remain in the application. Applicant will be entitled to rejoinder of those claims upon allowance of claim 1. MPEP § 821.04

Additionally, by the forgoing amendment, new claims 60-67 have been added. Thus, claims 1-5, 7-16, 55, 56 and 60-67 are currently pending for further action.

35 U.S.C. § 112, second paragraph:

In the recent Office Action, claims 4, 5, and 11 were rejected under 35 U.S.C. § 112, second paragraph. These claims have been carefully reviewed in light of the Examiner's comments.

While Applicant does not necessarily agree that any of these claims were indefinite as filed, the indicated claims have been amended herein to address the issues raised by the Examiner under 35 U.S.C. § 112, second paragraph. Following this amendment, all the

200315586-1

10/827,484

remaining claims are believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

With regard to claim 5, Applicant hereby states that the phrases in parenthesis are part of the claimed subject matter and would be understood by those of ordinary skill in the art.

Prior Art:

The recent Office Action makes three alternative rejections, each of which apply to independent claims 1 and 55. The three grounds of rejection are as follows.

(1) Claims 1-5, 7, 8, 10-15 and 55-56 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,653,996 to Hsu ("Hsu").

(2) Claims 1-5, 7-15, 55 and 56 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 4,976,964 to Schlossmann ("Schlossmann").

(3) Claims 1-3, 5, 7, 8, 12-15, 55 and 56 were rejected as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,958,378 to Waldrep ("Waldrep").

For at least the following reasons, these rejection should now be reconsidered and withdrawn.

Claim 1:

Independent claim 1 now recites:

A jettable solution comprising:  
a plurality of vesicles each comprising an inner membrane contained within and separate from an outer membrane; and  
a pharmaceutical payload encapsulated within said inner membrane of each of said vesicles.

Support for the amendment to claim 1 can be found in Applicant's originally filed specification at, for example, Fig. 4 and paragraph 0027.

200315586-1

10/827,484

In contrast, none of the cited prior art references teach or suggest the claimed jettable solution comprising vesicles “comprising an inner membrane contained within and separate from an outer membrane” with “a pharmaceutical payload encapsulated within said inner membrane of each of said vesicles.” This subject matter appears to be entirely absent from the cited prior art.

“A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection of claim 1 and its dependent claims based on Hsu, Schlossmann or Waldrep should be reconsidered and withdrawn.

Claim 7:

Claim 7 now recites:

A jettable solution comprising:  
a plurality of vesicles; and  
a pharmaceutical payload encapsulated within a central interior of each of said vesicles;  
wherein said plurality of vesicles each comprise an outer membrane comprised of two layers of molecules and wherein additional pharmaceutical payload is entrapped between said two layers of molecules of said vesicle outer membrane.

Support for the amendment to claim 7 can be found in Applicant’s originally filed specification at, for example, Fig. 3 and paragraph 0026.

In contrast, none of the cited prior art references teach or suggest the claimed jettable solution comprising “a pharmaceutical payload encapsulated within a central interior of each of said vesicles; wherein said plurality of vesicles each comprise an outer membrane comprised of two layers of molecules and wherein additional pharmaceutical payload is

200315586-1

10/827,484

entrapped between said two layers of molecules of said vesicle outer membrane.” This subject matter appears to be entirely absent from the cited prior art.

“A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection of claim 7 and its dependent claims based on Hsu, Schlossmann or Waldrep should be reconsidered and withdrawn.

Claim 55:

Independent claim 55 recites:

A jettable solution comprising:  
a water insoluble pharmaceutical payload; and  
a means for encapsulating said pharmaceutical payload in a center of vesicles disposed within a jettable solution.

Support for the amendment to claim 55 can be found in Applicant’s originally filed specification at, for example, paragraph 0059.

In contrast, the cited prior art references appear to teach away from the subject matter of claim 55. For example, Schlossmann expressly teaches that “water-soluable substances ... are enclosed in the aqueous inner volume of the vesicles,” rather than a water insoluble pharmaceutical payload as claimed.

None of the prior art references have been shown to teach a water insoluble pharmaceutical payload that is encapsulated “in a center” of vesicles disposed within a jettable solution. “A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single

200315586-1

10/827,484

prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection of claim 55 and its dependent claims based on Hsu, Schlossmann or Waldrep should be reconsidered and withdrawn.

Claim 16 was rejected under 35 U.S.C. § 103(a) over the teachings of either Hsu, Schlossmann or Waldrep, taken individually. For at least the following reasons, this rejection is respectfully traversed.

Claim 16 recites the jettable solution of claim 1 further comprising:

approximately 25 % vehicle;  
approximately 2 % vesicle forming component;  
approximately 3 to 6 % pharmaceutical payload; and  
water.

In contrast, the recent Office Action concedes that “[i]t is unclear from these references whether the compositions contain claimed amounts of vehicle, vesicle forming component and the payload.” (Action, p. 4). Nevertheless, the Office Action, without any supporting evidence, concludes that the recitations of claim 16 would have been obvious. Clearly no *prima facie* case of unpatentability has been made.

The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007):

“Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be

200315586-1

10/827,484

patented.” Quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

As set forth in MPEP 2143.03, to ascertain the differences between the prior art and the claims at issue, “[a]ll claim limitations must be considered” because “all words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385.

Therefore, to support a rejection of claim 16 under § 103, the Examiner must begin by identifying whether, how and where each of the limitations of the claim is taught or suggested by the cited prior art. Only then can the differences between the prior art and the claimed subject matter be assessed as required by *KSR* and *Graham*. Consequently, because the test for establishing obviousness has not been met, the rejection of claim 16 should be reconsidered and withdrawn.

The newly added claims are thought to be patentable over the prior art of record for at least the same reasons given above with respect to the original independent claims. Therefore, examination and allowance of the newly added claims is respectfully requested.

Conclusion:

In view of the foregoing arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments in future papers supporting the patentability of any of the claims, including the separate patentability of the dependent claims not explicitly addressed herein. In addition,

200315586-1

10/827,484


because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

The absence of a reply to a specific rejection, issue or comment in the Office Action does not signify agreement with or concession of that rejection, issue or comment. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP 2144.03.

If the Examiner has any comments or suggestions which could place this application in better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: May 9, 2008

  
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**CERTIFICATE OF TRANSMISSION**

I hereby certify that this correspondence is being transmitted to the Patent and Trademark Office facsimile number **571-273-8300** on **May 9, 2008**.  
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Rebecca R. Schow